In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-120V

(to be published)

K.G.,	*	Special Master Corcoran
Petitioner,	*	Filed: August 17, 2018
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Influenza Vaccine; Guillain-Barré Syndrome; Chronic Inflammatory Demyelinating Polyneuropathy; Table Claim; Limitations Period; Equitable Tolling; Mental Incapacity
Respondent.	*	

Thomas Reavely, Whitfield & Eddy, P.L.C., Des Moines, IA, for Petitioner.

Voris Johnson, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CASE AS UNTIMELY[1]

On January 24, 2018, K.G. filed a petition seeking compensation under the National Vaccine Injury Compensation Program.[2] The petition alleges that an influenza ("flu") vaccine K.G. received on October 12, 2011, caused her to experience Guillain-Barré syndrome ("GBS") and/or Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"). *See* Petition ("Pet.") (ECF No. 1) at 9-10.

[1] This Decision will be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the ruling will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Decision in its present form will be available. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

K.G. seeks an entitlement award based upon an injury she alleges was caused by a vaccine administered *seven years ago* – raising the question of whether the claim is time-barred under the Program's three-year limitations period for bringing claims. Section 16(a)(2). The Petition forthrightly acknowledges the above, but argues that K.G. was mentally incapacitated for almost four years (from 2012 until 2016), thereby establishing grounds for equitable tolling of the limitations statute. I directed the parties to brief the merits of Petitioner's equitable tolling argument. *See* Order, dated March 20, 2018 (ECF No. 9). Petitioner filed a brief in support of her position on June 14, 2018 (ECF No. 36) ("Brief"), Respondent opposed that position and requested dismissal on July 12, 2018 (ECF No. 37) ("Opp."), and then Petitioner filed a reply, dated July 19, 2018 (ECF No. 38) ("Reply").

Having reviewed the parties' submissions, I hereby determine that Petitioner's claim is untimely, and also that she has not established a basis for equitable tolling of the limitations period. As discussed in greater detail below, although there exists persuasive case law that supports tolling of the Vaccine Act's limitations statute due to mental incapacity (especially when that incapacity is associated with the claimed injury), it is far from a settled matter in the Program. More importantly, even assuming tolling were available under such circumstances, K.G. had a legal representative/guardian looking after her interests for a large portion of the time in which she was allegedly mentally incapacitated - suggesting that any tolling would have ended upon that person's appointment in 2014. Petitioner therefore is not excused from her failure to act diligently in exercising her rights, and the claim warrants dismissal.

Factual Background

Vaccination and Initial Evidence of Reaction/Neurologic Symptoms

Petitioner was born on October 21, 1962, and thus was 48 years old when she received the flu vaccine at issue. Ex. 8. The vaccine was administered to her at Mercy Medical Clinic in Johnston, Iowa on October 12, 2011, during pre-op treatment for a bilateral knee replacement surgery scheduled for November 21, 2011. Ex. 1 at 3; Ex. 3 at 497, 504, 512, 526, and 537; Ex. 6 ¶ 3. Petitioner had experienced "multiple" knee surgery procedures since 1979. Ex. 16 at 1. Prior to surgery, K.G.'s treaters observed that she exhibited an elevated heart rate between 92-108 beats per minute. Ex. 19 at 456; Ex. 2 at 226; Ex. 15 at 55. Later on in the day of her November surgery, Petitioner reported that her right leg and right toes were tingling, and she repeated such concerns on the day after. Ex. 3 at 512, 533, 620; Ex. 16 at 9.

Records from the post-operative period in the second half of November suggest that K.G. was experiencing pain associated with her recent procedure, but do not suggest at all any of the kinds of neuropathic symptoms typically associated with GBS (i.e., numbness, parasthesias, leg weakness). Ex. 16 at 9-13. Indeed, a December 1, 2011 record reported that, two weeks from

surgery (and now *seven* weeks from vaccination) Petitioner was "doing well," and memorialize no complaints of anything approximating a neuropathic symptom. *Id.* at 14.

K.G. continued to experience an elevated heart rate for the next several weeks. Ex. 2 at 236; Ex. 19 at 456. By December 6, 2011, she became concerned enough about the problem to contact her primary care provider, Dr. Amy Mitchell. Ex. 2 at 234. However, this record (like those from the second half of November) also makes no reference to peripheral neuropathic symptoms, and in fact states that Dr. Mitchell learned, after speaking by phone with K.G., that "[p]ain is well controlled *and she has no other symptoms*." *Id* (emphasis added). Dr. Mitchell saw Petitioner on December 8, 2011, and after examination diagnosed her with tachycardia, referring her to a cardiology specialist for further treatment, although these follow-up evaluations did not propose an explanation for her condition – and these records do not reference peripheral neurologic symptoms of any kind. *Id.* at 227, 236; Ex. 3 at 364, 484; Ex. 15 at 3, 51, 53.

In the meantime, K.G. experienced an alleged worsening of the nascent neurologic symptoms she claims to have reported around the time of her November surgery. Thus, on January 12, 2012, she reported to Dr. Mark Matthes, an orthopaedic surgeon at Iowa Ortho in Des Moines, Iowa, for a post-operative follow-up. Ex. 16 at 15. She now reported "decreased sensation" in her lower extremities. *Id* at 16. However, records from this visit mainly record an examination aimed at assessing Petitioner's recovery from knee surgery, and contain no suggestion of concerns (by Petitioner or Dr. Matthes) that any problems she faced were unrelated to that surgery. *Id.* at 15-16.

By early February, Petitioner returned to Iowa Ortho complaining of instability and pain in her left knee. Ex. 16 at 18. At a follow-up visit on February 23, 2012, she reported the same plus difficulty walking, which she claimed was "kind of a spontaneous event" that had only begun in January. *Id.* at 37. On exam, Petitioner exhibited "no gross sensory deficit," and reasonable extension of the left knee, accompanied with some strength deficit. *Id.* The treater who saw K.G. allowed for the possible need for an EMG to "rule out something like a neuropathy or some other sort of nerve injury," and planned to follow up with her after it was conducted in the next several weeks.

There is a subsequent ten-week gap in the records before the testing proposed in February was conducted on May 7, 2012. *See* Ex. 16 at 38. A nerve conduction study of her left tibial nerves resulted in an abnormal finding, with "prolonged distal latency." *Id.* at 39. In mid-May, K.G. returned to Iowa Ortho, and now described "hypersensitivity and lack of sensation on the bottom of both feet as well as from the knees down," along with tingling, [and] sharp burning sensation down both legs into [her] feet." *Id.* at 24. She reported that same month to her primary care treater that she was also experiencing "abnormal sensation in the fingertips bilateral hand affecting all fingers." Ex. 2 at 197.

Doctors initially diagnosed her with "tarsal tunnel [syndrome] on the right [leg]" (Ex. 16 at 24), but referred her to neurology specialists for further evaluation. Ex. 16 at 26; Ex. 2 at 198. That evaluation, performed on June 15, 2012, noted "progressive paresthesias involving all four extremities," "sensory changes" and "depressed" reflexes and indicated that these findings "may go with peripheral nerve disease such as diffuse peripheral neuropathy." Ex. 7F at 3232. Based upon the above, Petitioner's treating neurologists disputed the accuracy of the earlier tarsal tunnel syndrome diagnosis, and prescribed Gabapentin to treat Petitioner's burning and tingling sensations. Id. However, other than observing some lower extremity reflex abnormalities, the records from this neurologic evaluation do not suggest she was suffering from GBS, observing (a) an absence of "progressive parasthesias involving all four extremities," (b) "no objective motor findings," (c) and "no involvement of her upper extremities at this time." *Id*.

Throughout the summer of 2012, K.G. continued to experience similar symptoms, which she felt were worsening in intensity. Ex. 2 at 166; Ex. 20 at 5. On September 11, 2012, she went to the emergency room at Mercy Medical Center ("Mercy") in Des Moines, Iowa, and was hospitalized for her neurological symptoms at the recommendation of her primary care physician. Ex. 7I at 3847, Ex. 7F at 3168. By the fall, Petitioner's speech had also become affected, and she was diagnosed in October 2012 with ataxic dysarthria.[3] Ex. 13A at 267. She also began to experience increasing bladder control issues. Ex. 2 at 124.

After falling at home in November 2012, K.G. was transported by ambulance to Mercy. Ex. 2 at 113; Ex. 7D at 1531. She subsequently went into respiratory distress and was later admitted to Mercy on December 13, 2012, where she remained until mid-January 2013. Ex. 2 at 113; Ex. 21 ¶ 10; Ex. 7B at 457-59. At admission, Petitioner's initial diagnosis was "immune-mediated sensorimotor polyneuropathy," but the diagnosis was expanded to include CIDP at discharge. *Id.* at 457. Subsequent records from the winter of 2013 confirm the CIDP diagnosis. See., e.g., Ex. 18 at 60-63 (February 11, 2013 visit).

The discharge records make no mention of GBS. Petitioner, however, has pointed to other documents (primarily from records generated after post-hospitalization visits to her primary care physician, Dr. Mitchell) where a purported GBS diagnosis is referenced. *See,* e.g., Ex. 2 at 97 (January 28, 2013 visit), and 65 (April 13, 2013 visit).[4] However, these records

[3] Ataxic dysarthria is "dysarthria seen in patients with cerebellar lesions, characterized by slowness of speech, slurring, a monotonous tone, and scanning." *Dorland's Illustrated Medical Dictionary* (32nd Ed. 2012) ("*Dorland's*") at 575. Dysarthria is "a speech disorder consisting of imperfect articulation due to the loss of muscular control after damage to the central or peripheral nervous system." *Id.*

[4] Petitioner also points to a "vaccine assessment" form filled out at Mercy during her December 2012 hospitalization in which a box is checked in the "contraindications" section that reads "history of [GBS] within 6 weeks after a previous influenza vaccination," and the word "plasma" is written in next to it. Ex. 7B at 509. It appears based on this form that Petitioner was not at this time given the flu vaccine – but I do not conclude from this form that its existence reflects a reasoned, supportable treater opinion that, just because the box on the form was checked, *in fact*

contain no independent assessment of Petitioner's CIDP diagnosis or challenge to its validity, and do not relate any of her symptoms to the flu vaccine; indeed, some records from visits to Dr. Mitchell confirm the CIDP diagnosis. *Id.* at 105 (January 16, 2013 record noting that Petitioner had been "[h]ospitalized for 9 weeks and diagnosed with CIDP"). She continued to receive treatment for her neurologic symptoms into 2013 and beyond.

Mental Health Issues and Appointment of Guardian

Petitioner has alleged in this case that during the same time period in 2011-2012 that she was beginning to experience neuropathic symptoms allegedly associated with her receipt of the flu vaccine, she was contending with family problems that in turn took a toll on her mental health. Ex. 2 at 180, 189, 205; Ex. 7I at 3855. By the fall of 2012, she was beginning to report feeling depressed, and linked her state of mind to her declining physical health. Ex. 7F at 3168. She also began to develop substance abuse problems, taking an excessive amount of prescription medications. Ex. 2 at 118, 132, 169; Ex. 7F at 3169.

After her discharge from the hospital in January 2013, K.G.'s mental health deteriorated further, exacerbated by financial problems, and she continued to struggle with substance abuse. Ex. 11 at 231; Ex. 2 at 31, 62, 67; Ex. 21 ¶ 12; Ex. 23 ¶ 11. Eventually, her condition became so severe that she received in-patient treatment in May 2013 after being found unresponsive at home by a family member. Ex. 21 ¶ 16; Ex. 11 at 7; Ex. 21 ¶ 17. K.G. received medical treatment and was diagnosed with altered mental status. Ex. 11 at 4.

Unfortunately, K.G.'s mental problems thereafter became progressively worse, and she experienced more frequent occasions in which she could not display rational conduct or understanding of her immediate circumstances. Accordingly, in June 2013, she was admitted to Grinnell Health Care Center for in-patient care and rehabilitation services. Ex. 11 at 2-3; Ex. 3 at 833; Ex. 13A at 1. A month later, in July 2013, her sister obtained power of attorney on her behalf. Ex. 3 at 781-83. K.G. remained at the Grinnell Health Care Center until 2016. While an in-patient, treaters were able to observe and evaluate her behaviors. Eventually she obtained psychologic counseling from Dr. Daniel Ephraim Pott-Pepperman at Applied Behavioral Health Consultants. Ex. 13A at 499-500. In October 2013, after a thorough psychological examination, Dr. Pott-Pepperman diagnosed Petitioner with "Korsakoff's Amnesia," a syndrome characterized by neurocognitive impairment. Ex. 10 at 9-10.[5]

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a treater was opining that K.G. experienced GBS no later than the end of November 2011 – in the prior year.

[5] Korsakoff's Syndrome is "a syndrome of anterograde and retrograde amnesia with confabulation associated with alcoholic or nonalcoholic polyneuritis." The term is "currently used synonymously with the term amnestic syndrome." *Dorland's* at 1836.

In the ensuing period in which she was treated, Petitioner's family made the decision to place her under a guardianship and conservatorship. Ex. 4 at 1; Ex. 21 ¶ 23; Ex. 22 ¶ 10; Ex. 23 ¶ 12. They initiated the process for appointment of a guardian in Iowa state court in March 2014, and obtained the appointment later that same month, designating Petitioner's sister as guardian. Ex. 4 at 1, 16. Petitioner's sister's powers as guardian and conservator included control over K.G.'s financial and medical interests. Id. at 17.

Improvement and Termination of Guardianship

By the spring and summer of 2016, Petitioner's mental state showed encouraging signs of improvement. Ex. 13D at 1640; Ex. 4 at 141. After it was determined that K.G. could again function independently, the guardianship was terminated by the end of August 2016. Ex. 4 at 194. By late November 2016, Petitioner was again living with her husband in Grinnell, Iowa. Ex. 14 at 159.

Procedural History

As noted, this case was filed (along with a substantial number of medical records) in January 2018 – almost 18 months from the date K.G.'s in-patient mental health treatment ended, along with termination of her sister's guardian status. I held a status conference on March 20, 2018, during which I raised questions regarding the Petition's timeliness. Order, dated March 20, 2018 (ECF No. 9), at 1. Petitioner acknowledged that the claim's timeliness was an issue, but asserted that the limitations period should be subject to equitable tolling to take into account Petitioner's mental incapacity for a period of time from 2012-2016. *Id.* In response, I noted that the degree of tolling Petitioner asserted vastly exceeded what had previously been allowed in other Vaccine Program cases, but I informed Petitioner that I would provide her with an opportunity to make her case. *Id.* at 2. The parties subsequently filed the aforementioned briefs, concluding the process in mid-July of this year.

Petitioner contends that she was mentally incapacitated such that she could not protect her own legal interests from November 9, 2012 (the date when she first was taken to the hospital after falling at home), to May 10, 2016 (when she underwent a mental examination and showed positive results) - a period of 1,278 days, or approximately three and one-half years. Brief at 36. Based upon this assertion, Petitioner adds 1,095 days (representing the Vaccine Act's three-year statute of limitations) for a total period of 2,373 days after the date of her vaccination in which Petitioner argues she had to file her claim before it would be untimely. *Id.* at 39-40. Because the Petition was filed on January 24, 2018 -- 2,265 days after the date of her vaccination -- Petitioner argues that her claim is timely. *Id.* at 40.

Respondent advances three counter-arguments regarding the untimeliness of K.G.'s claim. First, Respondent contends that equitable tolling on the basis of mental incapacity should

not be available to Vaccine Program petitioners *at all* - or, at a minimum, should be unavailable during a period in which the petitioner was represented by an appointed legal guardian able to pursue a petitioner's legal interests. Opp. at 6. In so arguing, Respondent emphasizes that the Federal Circuit's *Barrett* decision (relied upon in *J.H.* and *Gray*) was heavily dependent on veterans benefits laws and the policy goals behind them, which are not congruent with the Vaccine Act. *Id.* at 7. Second, Respondent maintains that Petitioner's proposed period of incapacity is too long, and that application of a more reasonable tolling period would still result in the Petition being untimely. *Id.* at 9. Finally, Respondent argues that tolling would be improper because the late filing was not the "direct result" of Petitioner's mental incapacity. *Id.* at 15.

In her Reply, Petitioner contends that prohibiting equitable tolling in Vaccine Program cases would be inconsistent with past precedent as well as the goals of the Program itself. Reply at 3. Second, Petitioner argues that tolling is available even when a claimant has a legal representative, therefore mooting from consideration the fact that K.G. had such a representative during a large portion of her mental incapacitation. *Id.* at 8. Third, Petitioner maintains that refusing to apply equitable tolling in this case would be inconsistent with how other federal courts have applied the equitable tolling doctrine. *Id.* at 12. Finally, Petitioner contends that she has demonstrated that her late filing was the direct result of her mental incapacity. *Id.* at 16.

Relevant Legal Standards

The statute of limitations prescribed by the Vaccine Act is three years, or thirty-six months. Section 16(a)(2). The statute begins to run from the manifestation of the first objectively cognizable symptom, whether or not that symptom is sufficient for diagnosis (or even recognized by a claimant as significant). *Id; Carson v. Sec'y of Health & Human Servs*., 727 F.3d 1365, 1369 (Fed. Cir. 2013). Special masters have appropriately dismissed cases that were filed outside the limitations period, even by a single day or two. *See, e.g., Spohn v. Sec'y of Health & Human Servs.*, No. 95-0460V, 1996 WL 532610 (Fed. Cl. Spec. Mstr. Sept. 5, 1996) (dismissing case filed one day beyond thirty-six-month limitations period), *mot. for review denied*, slip. op. (Fed. Cl. Jan. 10, 1997), *aff'd*, 132 F.3d 52 (Fed. Cir. 1997).

The U.S. Supreme Court has observed that equitable tolling of a limitations period should be permitted "sparingly." *Irwin v. Dep't of Veterans Affairs*, 498 U.S. 89, 96, (1990). To obtain it, a litigant must establish ''(1) that he has been pursuing his rights diligently, and (2) that some extraordinary circumstance stood in his way'' to filing the claim. *Pace v. DiGuglielmo*, 544 U.S. 408, 418 (2005). The appropriateness of permitting equitable tolling is, however, to be determined on a case-by-case basis without rigid application of such overarching guidelines.

Holland v. Florida, 560 U.S. 631, 649–50 (2010); *accord Arctic Slope Native Ass'n v. Sebelius*, 699 F.3d 1289, 1295 (Fed. Cir. 2012).

The Federal Circuit has held that the doctrine of equitable tolling can apply to Vaccine Act claims in limited circumstances. *See Cloer v. Sec'y of Health & Human Servs*., 654 F.3d 1322, 1340-41 (Fed. Cir. 2011). To date, these circumstances have been enumerated to include fraud and duress -- but not, for example, lack of awareness on a petitioner's part that she might have an actionable claim. *Cloer*, 654 F.3d at 1344-45 (it is well-settled in the Program that tolling of the Vaccine Act's statute of limitations period is not triggered "due to unawareness of a causal link between an injury and administration of a vaccine").

The Federal Circuit has not yet stated whether a claimant's mental incapacity should constitute another basis for tolling. Nevertheless, on a handful of occasions special masters have been asked to toll the limitations period for this reason. One of the first such instances occurred in *J.H. v. Sec'y of Health & Human Servs.,* 123 Fed. Cl. 206 (2015), *on remand*, No. 09-453V, 2015 WL 9685916 (Fed. Cl. Spec. Mstr. Dec. 21, 2015). In that case, a petitioner alleged that he was injured by vaccines received in March and April 2006, with symptoms beginning in early June of that same year. *J.H.*, 123 Fed. Cl. at 208. But the claim was filed in July 2009 – rendering it literally untimely (albeit by approximately one month) under the Act's limitations statute, and leading the special master presiding over the case to dismiss it. *Id.* at 215.

Petitioner thereupon filed a motion for review, arguing that in the period between onset and filing of the claim, he had suffered from serious mental health problems that constituted reasonable grounds for equitable tolling of the statute. *J.H.*, 123 Fed. Cl. at 216. The Court, reviewing the medical record, found that the special master had not fully evaluated that record (which documented in detail the petitioner's mental health problems), and remanded the case so that the availability of equitable tolling could be determined. *Id.* at 219. Despite the implication of the holding, the *J.H.* Court acknowledged there was limited controlling authority addressing whether mental illness was a sufficient justification for equitable tolling, given that the sole Federal Circuit precedent relevant to the issue – *Barrett v. Principi*, 363 F.3d 1316, 1318-20 (Fed. Cir. 2004) – involved veteran's benefits statutes rather than the Vaccine Act.[6] *Id.* at 216.

[6] *Barrett* specifically stated that a veteran claimant could obtain equitable tolling for mental illness by demonstrating that his "failure to file was the direct result of a mental illness that rendered him incapable of 'rational thought or deliberate decision making,' or 'incapable of handling [his] own affairs or unable to function [in] society.' A medical diagnosis alone or vague assertions of mental problems will not suffice." *Barrett*, 363 F.3d at 1321 (citations omitted).

The Federal Circuit in *Barrett* also emphasized that permitting tolling for mental incapacity was consistent with the policy goals of the veterans benefit system, which provides an entitlement to those citizens who have given military service to their country, and that "it would be both ironic and inhumane to rigidly implement [the relevant limitations period] because the condition preventing a veteran from timely filing is often the same illness for which compensation is sought." *Barrett*, 363 F.3d at 1321.

Indeed, the Court specifically noted that "the issue of whether the *Barrett* standard should be applied in Vaccine Act cases is not before the court," because the parties had not contested it in the motion for review. *Id.* at 216 n.8.

On remand, the special master reevaluated the evidence, and in doing so found that tolling was appropriate during the intervening period in which the petitioner was "not capable of managing his affairs" due to mental illness. *J.H.*, 2015 WL 9685916, at *24. However, the special master noted that the lack of Federal Circuit guidance on the subject meant that the conclusions reached therein might warrant revisiting in the future. *Id.* In addition (and of relevance herein), the special master discussed at some length whether the petitioner's mental illness meant he should obtain a legal representative going forward – given that the Vaccine Rules expressly permit claimants to have guardians or other duly-authorized individuals pursue claims on an injured individual's behalf. *Id.* at *21-23.

A subsequent special master's decision, *Gray v. Sec'y of Health & Human Servs.,* No. 15-146V, 2016 WL 787166 (Fed. Cl. Spec. Mstr. Feb. 4, 2016), is consistent with *J.H*. There, a petitioner alleged that a flu vaccine she received in October 2011 caused neurologic symptoms that began that November. *Gray,* 2016 WL 787166, at *1. She filed her claim on February 18, 2015 – three months after the limitations period would have run from alleged onset in November 2011 – but argued that the period should be tolled for a five-month period[7] to account for a timeframe in which she was allegedly mentally incapacitated. The special master embraced the reasoning of *J.H.* and found that the petitioner should have the opportunity to prove that her incapacity met the standard set in *Barrett.* 2016 WL 787166, at *6-7. After the marshalling of the evidence on that point, the special master found that tolling was appropriate, and therefore that the claim was timely. *Gray v. Sec'y of Health & Human Servs.,* No, 15-146V, 2016 WL 6818884 (Fed. Cl. Spec. Mstr. Oct. 17, 2016).

Even more recently, the Court of Federal Claims weighed in again on the availability of equitable tolling for mental incapacity – but reached a result somewhat contrary to *J.H.* and *Gray. Clubb v. Sec'y of Health & Human Servs.,* 136 Fed. Cl. 255 (2018). In *Clubb,* a petitioner appealed a special master's finding that his case - filed in August 2015, and based upon a July 2012 vaccination – was untimely *by one day* only, arguing that physical and mental impairments relevant to his alleged vaccine-caused injury had incapacitated him, and that therefore the statute should be equitably tolled. *Clubb,* 136 Fed. Cl. at 263. The special master had observed that the impairment in question, while actual, was not demonstrated to have prevented him from pursuing his legal rights.136 Fed. Cl. at 265.

[7] Both *Gray* and *J.H.* employed a "stop-clock" approach in calculating the overall limitations period, referencing Federal Circuit law in support. *Gray v. Sec'y of Health & Human Servs.,* No. 15-146V, 2016 WL 787166, at *6 (Fed. Cl. Spec. Mstr. Feb. 4, 2016), *citing Checo v. Shinseki*, 748 F.3d 1373, 1379 (Fed. Cir. 2014). Under this approach, "the statute is tolled for the period of severe mental disability and begins to run again when the petitioner is capable of asserting a claim." *Gray,* 2016 WL 787166, at *6.

The Court affirmed dismissal, largely based on its determination that the special master had appropriately found that (assuming tolling was available) the petitioner's impairment was insufficient to justify tolling. *Clubb,* 136 Fed. Cl. at 264-66. However, the Court also noted that the policy arguments *against* allowing equitable tolling in the Vaccine Program for mental or physical incapacity were compelling. *Id.* at 263-64. The Court thus credited as persuasive Respondent's arguments that (a) there was no Federal Circuit authority supporting the contention that equitable tolling for mental or physical impairment was appropriate in the context of the Vaccine Act, (b) the Vaccine Act expressly permitted claims to be brought *on behalf of* injured parties by authorized representatives, and (c) the Act also allowed compensation for injuries that could directly produce cognitive impairment, such as encephalopathy, but did not exclude such claims from the three-year limitations period – all suggesting that the Act envisioned circumstances in which a claimant would need to act to assert a legal cause of action despite mental incapacity. *Id.* As a result, the Court expressed "misgivings" about the appropriateness of allowing this kind of equitable tolling in Vaccine Program cases. *Id.* at 264.

ANALYSIS

I. Tolling the Limitations Period for Petitioner's Mental Incapacity Would not Render the Claim Timely Filed

Based upon the filed medical records, Petitioner has established that she was mentally incapacitated for a lengthy period of time after her vaccination. However, whether equitable tolling on the grounds of mental incapacity should be available to Program claimants remains an unsettled question. Decisions like *J.H.* and *Gray* provide reasoned grounds for allowing tolling in the case of mental incapacity. In addition, the flexible, case-by-case manner in which requests for equitable tolling are to be evaluated supports permitting claimants to attempt to substantiate their tolling arguments with evidence, rather than dismissing such attempts categorically. At the same time, the Court's recent decision in *Clubb* makes valid points as to why the Vaccine Act might *not* countenance this kind of tolling. *See* Opp. at 6-8. And, most fundamentally, there is no Federal Circuit precedent instructing how to apply equitable tolling under these circumstances.

Despite the above, I need not add my two cents to this debate – for the untimeliness of Petitioner's claim is manifest even if I assume that equitable tolling is available for mental incapacity.

To evaluate application of tolling to this case, I must determine (a) the nature of Petitioner's injury, (b) when Petitioner's claim accrued, (c) whether there was a period of time in which the statute ran before it was subsequently tolled due to mental incapacity, and finally, (d) if the date the case was ultimately filed still fell within the three-year period even after taking into account tolling.

As noted above, Vaccine Act claims accrue at the first manifestation of symptoms, regardless of whether those symptoms are understood (by a petitioner or even treaters) to evidence the complained-of injury. Here, Petitioner alleges she experienced some form of peripheral neuropathy after her October 2011 vaccination, and although she has termed it GBS in her Petition, I find that the medical record evidence only supports a diagnosis of CIDP. First, the CIDP diagnosis was *actually made* by treaters. Ex. 7B at 457-59. GBS, by contrast, is only referenced in passing, subsequent to Petitioner's late 2012 hospitalization, and those references lack any analytical support and do not reflect reasoned treater views. Ex. 2 at 65, 97.

Second, the Petitioner's symptoms are inconsistent with GBS, which is well understood to be acute and monophasic, reaching nadir in four to six weeks in most instances. *Blackburn v. Sec'y of Health & Human Servs.*, No. 10-410V, 2015 WL 425935, at *23 (Fed. Cl. Spec. Mstr. Jan. 9, 2015). CIDP, by contrast (which is not simply a GBS variant, despite its parallel character as a peripheral neuropathy), can wax and wane over a far longer period of time. *Blackburn*, 2015 WL 425935, at 31. Petitioner's medical history reflects a lengthy, halting course progressing from the date of her flu vaccine in October 2011 until her CIDP diagnosis in late 2012, and such evidence persuasively establishes CIDP as the only cognizable neuropathic injury.[8]

I further conclude that the record suggests onset of K.G.'s CIDP occurred no later than February 2012. Although Petitioner reported experiencing "decreased sensation" in her lower extremities in January 2012 (Ex. 16 at 16), these feelings are most credibly linked to Petitioner's fall 2011 surgery, and the records at this time do not establish a neuropathic injury. By February, however, Petitioner's complaints of leg numbness were seen by treaters as the basis for an EMG or nerve conduction study, the kind of tests deemed highly probative of peripheral neuropathic injury. *See Simanski v. Sec'y of Health & Human Servs.*, No. 03-103V, 2013 WL 7017568 (Fed. Cl. Spec. Mstr. Aug. 20, 2013). Such an onset is also consistent with CIDP, which can present erratically, but which (in the views of prior experts testifying in the Program) will typically first present within two or three months post-vaccination. *See*, e.g., *Strong v. Sec'y of Health & Human Servs.*, 15-1108V, 2018 WL 1125666, at *7, 21 (Fed. Cl. Spec. Mstr. Jan. 12, 2018) (noting that two months would be an appropriate onset timeframe for CIDP post-vaccination, whereas 4-5 months would be too long). Thus, all things being equal, this case should have been filed by mid-February 2015 – not almost three years after that date, in 2018.

[8] I also note that, for purposes of my present analysis, it *benefits* Petitioner to treat her injury as CIDP. Given its more acute nature, GBS would be expected to manifest in no more than six to eight weeks from vaccination at longest – meaning the start of the limitations period in this case would have to have begun no later than November or December 2011, increasing the amount of time that the statute would have run before K.G.'s incapacitation. Assuming the injury to be CIDP is not only more consistent with the record, but also allows me to find onset to have begun slightly later.

I next must determine when the limitations statute stopped running due to K.G.'s mental incapacity, applying the "stop-clock" approach for calculating the overall limitations period. *Checo v. Shinseki*, 748 F.3d 1373, 1379 (Fed. Cir. 2014); *Gray*, 2016 WL 787166, at *6. Petitioner contends that the proper date for the start of tolling was November 9, 2012. Mot. at 36. The record reflects that on that date, Petitioner was found by her sister and her sister's husband after a fall, and that because two family members were unable to help her, an ambulance was called which took Petitioner to the hospital. Six days later, Petitioner went into respiratory distress (later diagnosed as Acute Respiratory Distress Syndrome), requiring use of a ventilator and feeding tube. Ex. 7D at 1540, 1846. During this time, Petitioner notes that she was placed in wrist restraints due in part to her cognitive impairment. *Id.* at 1623. Petitioner was ultimately discharged on January 11, 2013, approximately two months later.

Despite the above, evidence subsequent to November 2012 suggests that Petitioner's overall mental status had not yet so declined that she could be said to be fully incapacitated. Although the record clearly establishes that Petitioner's mental health may have been a concern around the time of her late 2012 hospital stay, her treaters were then more concerned with her ongoing physical symptoms than her mental symptoms. In addition, K.G. improved to a point where she was allowed to return home. And a February 11, 2013 follow-up appointment for neuropathy and numbness noted Petitioner's mental state as "alert," and that her "judgment and insight were intact and appropriate," and she had an "appropriate fund of knowledge." Ex. 18 at 61-62.

I therefore do not conclude that November 9, 2012, is an appropriate date to begin tolling. Instead, the record best establishes that K.G. did not become sufficiently mentally impaired so as to stop the running of the limitations period before May 26, 2013 – when she was found collapsed at home a second time. Only after this incident was she hospitalized as an in-patient for her mental problems, and subsequently diagnosed that fall by Dr. Pott-Pepperman with a form of amnesia. Her substance abuse and other conduct before this time does not establish sufficient mental impairment, despite its alarming nature. Based on this determination, the limitations period on Petitioner's claim ran for approximately 15 months before stopping, or from February 2012 to May 2013 – leaving 21 months left before the claim would be time-barred.[9]

Finally, I must determine the date the limitations countdown started again. Petitioner proposes May 2016 as that start-up time, based on her documented mental health improvement. But the record more persuasively establishes that the "clock" started again in March 2014, when Petitioner's sister was appointed as her legal guardian.

[9] Acceptance of Petitioner's proposed tolling start date would not render her claim timely. With an onset of symptoms in February 2012, Petitioner's time to file would have elapsed only nine months before tolling under Petitioner's theory. But, given my determination (discussed below) that tolling ceased in March 2014, K.G. would only have an additional 27 months to file – or by June 2016 – meaning that the claim would still be untimely.

The record establishes that the appointment of K.G.'s sister as guardian in this case empowered her to act on Petitioner's behalf. Specifically, as noted in Petitioner's submissions, the guardianship/conservatorship appointment gave K.G.'s sister authority to make decisions with respect to Petitioner's physical wellbeing and otherwise. Ex. 4 at 17. Concerning conservatorship powers, the "Notice of Your Rights" document (required by statute to be provided to the protected person, and mailed along with the petition for appointment of guardian and conservator), states that "[i]f a conservator is appointed, the conservator may, without court approval, . . . *sue and defend any claim by or against you* . . . ." *Id.* at 3 (emphasis added). This language mirrors that of Iowa Code § 633.646, which provides, in pertinent part, that "[t]he conservator shall have the full power, without prior order of the court, with relation to the estate of the ward: 1. To collect, receive, receipt for any principal or income, and to enforce, defend against or prosecute any claim by or against the ward of the conservator; *to sue on and defend claims in favor of, or against, the ward or the conservator*" (emphasis added). Indeed – it may be particularly appropriate that an individual who was mentally impaired after vaccine administration have such a representative litigating the claim for her. *See J.H.*, 2015 WL 9685916, at *5-6. Petitioner's guardian was thus a person with the capacity to bring her vaccine injury claim, even if Petitioner's individualized mental incapacity continued after the appointment.[10]

Petitioner's arguments that the appointment of a guardian has no bearing on the availability of equitable tolling are misplaced. She cites *J.H.* as so holding – but the facts of that case are disparate to the present circumstances. There, Respondent argued that the adult petitioner *could* have had a parent appointed as guardian during his incapacity, leading the special master to discuss the distinction between an existing representative's *right* to file suit for another, versus the obligation of a *potential*, qualified person to become a legal guardian or representative for another who lacked such a guardian. *J.H.*, 2015 WL 9685916, at *6. The special master emphasized the importance of protecting the rights of such an unrepresented individual under the Vaccine Act, rather than imposing a duty on an otherwise-qualified individual to become a legal representative. *Id.* at *7.[11] Here, by contrast, it cannot be disputed

[10] Indeed, in discussing why equitable tolling for mental incapacity should be allowed in Program cases, the special master in *Gray* emphasized that authority existed elsewhere highlighting the importance of a representative's appointment in measuring the limitations period. *Gray*, 2016 WL 787166, at *5, *citing Clifford v. United States*, 738 F.2d 977 (8th Cir. 1984) (individual's medical malpractice claim under Federal Tort Claims Act for wrongful coma did not accrue until time of representative's appointment, since that was time person with requisite knowledge of injury had legal duty to act for the injured party; coma prevented injured party from being aware of claim entirely).

[11] Other courts have suggested that appointment of a guardian is actually *evidence* that a person was mentally incapacitated. *See*, e.g., *Speiser v. Dep't of Health & Human Servs.,* 670 F. Supp. 380, 385 (D. D.C. 1986) (claimant seeking to establish mental incapacity basis for tolling of statute of limitations could do so by establishing that she "took measures to let someone else handle her affairs as might be done for someone who is *non compos mentis*"). But this does not mean that any tolling of a limitations statute continues unabated even *after* the guardian's or representative's appointment – and Petitioner in this case has offered no persuasive authority so holding.

that K.G. *did* have a legal representative for a substantial period, and that this individual had full authority to bring a legal claim on her behalf.

Accordingly, I find that the limitations period governing Petitioner's claim restarted in March 2014. Since the 36-month period had only elapsed 15 months by this date, there remained only 21 months – or until December 2015 – to file the case. Because it was not filed until January 2018, it is untimely by over two years.

I also do not find that the broader equitable considerations at play in evaluating a request to toll a limitations period favor Petitioner's tolling request. In particular, I find that Petitioner and/or her legal representative did not act diligently in exercising her legal rights. Although some cases like *J.H.* suggest that diligence is not relevant to the specific period of a claimant's mental incapacity, a claimant's diligence *can* be evaluated during the period in which the petitioner or her authorized representative had capacity to bring a Vaccine Act claim – as well as when the petitioner was not so incapacitated.

Here, and based upon my onset finding of February 2012, Petitioner had the capacity to bring her claim for more than a year before she lost the mental facilities to act in May 2013. Then, her representative held a guardianship position for over two years without taking action, even though the record establishes that Petitioner's alleged vaccine-caused symptoms already existed. Given that these symptoms existed for nearly *two years* before the representative's appointment in March 2014, it is reasonable under such circumstances to hold that legal representative – who had sufficient authority to act on Petitioner's behalf in numerous regards - responsible for bringing such a claim in a more timely manner. This – along with the fact that this claim remained unfiled for an additional year and a half more even *after* Petitioner regained mental competency – does not constitute diligence thwarted by circumstances beyond one's control.[12]

The lack of diligence is only underscored when the injury in question is taken into account. Claims that the flu vaccine caused GBS, CIDP, or some other form of peripheral neuropathy are legion in the Vaccine Program, and flu-GBS cases have been deemed to have sufficient medical legitimacy to cause amendment of the Table to add them as a specified injury that can be established without a showing of causation. 42 C.F.R. § 100.3(a); 82 FR 6294-01,

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[12] Whether Petitioner's alleged vaccine-caused CIDP is related to her mental incapacity presents a closer call. The medical records do not establish that her neuropathic injuries produced directly a brain or central nervous system injury that could be medically associated with the same process that might in theory produce the kind of demyelination resulting in GBS or CIDP. However, Petitioner has maintained that her decline in physical health post-vaccination contributed to her depression and substance abuse, and it is reasonable to conclude from this that the vaccine injury alleged did play a role in her subsequent mental incapacity. Regardless, I need not resolve this question, given the overall untimeliness of the claim's filing despite the existence of a legal representative with the capacity to have filed the claim for Petitioner.

2017 WL 202456 (Jan. 19, 2017). It should not take a party over six years to allege such a claim unless exceedingly rare circumstances are established. While Petitioner's personal suffering is self-evident and tragic, it has not been demonstrated herein to constitute the kind of unique situation in which equity would demand tolling.

II. The Lookback Provisions of the Table Revision Adding GBS as a Table Injury Do Not Save Petitioner's Claim

Although I have determined that Petitioner's claim is untimely regardless of equitable tolling, I note that Petitioner's claim is formally styled as a Table claim alleging GBS as the injury. Petition at ¶ 76. In an abundance of caution, I will therefore also evaluate whether the recent revisions to the Vaccine Act to add GBS as a Table Injury provide an alternative basis for finding the claim timely.

Effective March 21, 2017, the Vaccine Table was amended to include GBS as a specified injury for individuals receiving the flu vaccine. 82 FR 6294-01, 2017 WL 202456 (Jan. 19, 2017). The enacting regulations specified that this new Table claim was subject to the Act's existing three-year limitations period, but included a lookback provision, providing that any individual who alleged to have experienced injury occurring not more than eight years before the effective date of revision (March 21, 2017) could file suit based on the new Table claim within two years of the effective date. 42 U.S.C. § 300aa-16(b).

Petitioner's claim was filed on January 24, 2018 – clearly within two years of the addition of the flu-GBS claim to the Table. Moreover, she alleges GBS as her injury, with onset in November 2011 – a date within eight years of the Table amendment's effective date. Thus, Petitioner's claim could be timely based on this lookback provision despite her inability to establish grounds for equitable tolling.

There is, however, a significant bar to Petitioner making use of this lookback provision to save her claim. The evidence submitted in this case, which is already voluminous, overwhelmingly does *not* support the conclusion that she suffered from GBS, but rather CIPD, an exclusionary criteria under the Table's Qualifications and Aids to Interpretation ("QAI"). 42 C.F.R. § 100.3(c)(15)(iv) (stating, in pertinent part, that "[e]xclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of the following conditions: chronic immune demyelinating polyradiculopathy (CIDP) . . ."). As noted above, although GBS is referenced in offhand fashion in some medical records, Petitioner ultimately received a formal diagnosis of CIDP. Ex. 7B at 457-59; Ex. 18 at 60-63.

Moreover, and independent of diagnosis, Petitioner's course of injury is wholly inconsistent with GBS, which is known to be acute and monophasic, rapidly reaching nadir after

initial insult (whether caused by infection or vaccination less commonly). *See Reichert v. Sec'y of Health & Human Servs.*, No. 16-697V, slip op. at 21 (Fed. Cl. Spec. Mstr. Aug. 2, 2018). K.G. received the flu vaccine in October 2011; experienced some possibly neurologic symptoms a few weeks later that were more likely associated with her November 2011 knee replacement surgery; and then did not truly experience the symptoms classically associated with a peripheral neuropathy until February 2012 (at earliest) – approximately *four months* after vaccination on October 12, 2011, and thus well outside what special masters have found to be a reasonable timeframe for GBS onset. *See, e.g.*, *Barone v. Sec'y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (eight weeks is the longest reasonable timeframe for a flu vaccine/GBS injury). Arguably, the timeframe is even longer, since she was not diagnosed with any kind of possible neuropathic injury before May 2012 (Ex. 16 at 24-26), and only sought emergency treatment in the fall of 2012 – now a year post-vaccination. Brief at 7. This course most persuasively describes the waxing/waning nature of CIDP – not GBS – and therefore the existing record does not at all support the conclusion that a claim based on GBS as the injury could possibly succeed.[13]

For similar reasons, Petitioner's claim also fails a second flu-GBS Table requirement involving symptom onset. A Table claim of flu vaccine-caused GBS must establish the first symptom or manifestation of onset occurred 3-42 days after vaccination. 42 C.F.R. § 100.3. This means that because Petitioner was vaccinated on October 12, 2011, her GBS must have presented in some form by November 23, 2011. However, the medical records do not permit the finding that more likely than not her neurologic symptoms (assuming for argument that they *did* reflect GBS) began any earlier than February 2012. Prior to this date, she complained only intermittently of leg pain and tachycardia (a symptom not associated with GBS); after, she noted "decreased sensation" in her legs, and then obtained testing results that clearly documented the neurologic nature of her injury. Onset in February is too long outside the 42-day window to successfully establish a Table injury based on a vaccine received the prior October.

CONCLUSION

This case is dismissed because it was not filed within the three-year statute of limitations. The Clerk shall enter judgment accordingly.

[13] For such reason, and based upon my review of the extensive records filed, I would find that a claim positing GBS as the injury in this case would lack reasonable basis (meaning fees generated in prosecution of the case should not be reimbursed) *even if* it had been filed in a timely manner. In the face of such evidence, an expert could not reasonably, credibly establish that her injury is not as her treaters ultimately determined.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Special Master